

REMARKS/ARGUMENTS

This Amendment is submitted in response to the first Official Action of September 27, 2004. Reconsideration and allowance of claims 1-15 and 17-44 remaining in the application are respectfully requested.

The Office Action objects to claims 5-14 under 35 U.S.C. §112 (second paragraph) indicating that those claims lack antecedence for "triggering". This rejection is not understood. Reference is made to independent claim 1, at line 12, where a clear antecedent is provided. Clarification or withdraw of the objection to claims 5-14 is requested.

The Office Action rejects claims 1, 3-5, 8, 11, 12 and 14 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,275,6221 to Mehra. This rejection is respectfully traverse.

Before it is appropriate to reject a claim based on 35 U.S.C. §102(b), the single reference relied upon must, within its four corners, contain a disclosure of each and every limitation of the claim that is sought to be anticipated. The Mehra '621 patent fails in this regard. As now amended, independent claim 1 recites "a sensing circuit configured to receive signals indicative of the depolarization events from a first electrode positioned within a sensing channel for an atrium of the patient's heart and a second electrode positioned within a sensing channel for the ventricle of the patient's heart". The Mehra '621 patent describes an implantable cardioverter that includes a right ventricular lead 106 with electrodes 108 and 116 placed in the right ventricle and a subcutaneous electrode 114 which constitutes a return electrode for energy delivered from the defibrillation electrode 110 also located in the right ventricle. No provision is made for either pacing or sensing in an atrial chamber. See column 5, lines 7-18 of the '621 patent. Without any provision for atrial pacing/sensing, the '621 patent cannot anticipate independent claim 1 nor any of the claims dependent there from. Thus, the Section 102(b) rejection based upon the Mehra '621 patent should be withdrawn.

The Office Action also rejects claims 1, 3-9, 11, 12, 14, 15, 17, 19, 20, 24-30, 34 and 41 under 35 U.S.C. §102(b) based on U.S. Patent 5,643,326 to Weiner et al. This rejection is also respectfully traverse as failing to anticipate the claims indicated.

To understand the differences between the dual chamber pacemaker described in the '326 patent and the present invention, it is important to recognize the difference between blanking periods and refractory periods. Because it is not possible to distinguish the desired components of an electrogram from unwanted signals by filtering alone, pacemaker pulse generators use the expect timing of atrial and ventricular activation as a means of improving signal discrimination. To ignore the depolarizations and after-potential induced by pacing stimuli, the atrial and ventricular sensing amplifiers employed are disabled for a brief period after the pacing stimulus. This interval is called the "blanking period" and for the ventricle is generally about 20-50 ms in duration. This temporary inactivation prevents sense amplifier saturation by the high-input voltage of the pacing stimulus. Saturation of the amplifier would necessitate a period of recovery before the amplifier can again become functional. The blanking of the amplifier allows it to be re-enabled immediately without the delay of recovery. Thus, if an electrical event occurs within this blanking period, it will not be sensed. Conventionally, in dual-chamber pacing systems, both the atrial and ventricular sense amplifiers are blanked immediately after a pacing stimulus in either chamber.

To avoid sensing of T-waves and far-field events by the ventricular sense amplifier, a programmable "refractory period" is employed. During the refractory period, the sense amplifier remains enabled because amplifier saturation is not expected to occur. The pulse generator, however, will not respond to electric signals that exceed the programmed sensitivity threshold value during the refractory period. Events during the refractory period may be sensed for tachyarrhythmia detection algorithms, but generally do not alter the timing cycles.

In applying the Weiner et al. '326 patent disclosure to applicants' claims, the Office Action equates blanking periods with refractory periods. As explained above, this is not the case. During atrial blanking, ventricular events can be detected since at this time only the atrial sense amplifier is shut off.

Claim 1, as amended, recites:

" a controller configured to receive data from the sensing circuit and to control the pulse generator, wherein the controller prevents the use of data to detect intrinsic depolarization events during a plurality of programmable refractory periods in timed relation relative to a sensed triggering event in one of a plurality of programmably selectable sensing channels."

The '326 patent is silent as to the ability to programmably select the sensing channel in which the plurality of programmable refractory periods are active. As such, claims 1-14 should be found allowable. Claims 15 and 17-24 also are not anticipated by the Weiner et al. '326 patent. Referring to claim 15, it does not disclose a controller that can establish first and second refractory periods of sensed events for programmably pre-selected chambers during the cardiac cycle. As such, claim 15 and claims 17-24 that depend from claim 15 should now be allowed.

Independent claim 25 also calls for a controller have a means for defining both a refractory period and a floating refractory period for a predetermined cardiac cycle in a programmably selectable heart chamber. The control structure and algorithm described in the '326 patent does not have such a controller and, for that reason, is not anticipated. With the allowance of claim 25, dependent claims 26-34 can also be allowed. In that claims 35-40 were not rejected based on the Weiner et al. '326 patent, those claims are considered to be patentable there over.

Concerning claim 42, the method therein described provides for the establishment of a delay value beginning with a triggered event and terminating at a time in the cardiac cycle before which the unwanted potential is predicted not to occur along with the step of programming a duration of the blanking or refractory period that begins at the end of the aforementioned delay value and lasts for a period of time during which the unwanted potential is predicted to occur. Examination of Figures 3-6 of the '326 patent immediately shows that there is not interval between an atrial refractory period and the atrial blanking period in which sensing can occur. A major aspect of the present invention, as claimed, is to provide a time window between the first and second refractory periods during which depolarization can be sensed. In this regard, it is

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respectfully requested that the examiner again review applicants' specification beginning at page 5, line 30, through page 6, line 19.

It is submitted that claim 41 is neither anticipated nor rendered obvious by the prior art and should be allowed.

Newly added claims 42-44 are dependent claims that have been added to positively claim the aspect of the present invention wherein the floating refractory period is retriggerable to extend its length if a triggering event is detected during the floating refractory period. This aspect of the invention was inadvertently not claimed at the time the present application was filed.

Claims 1-22 and 24-41 have been rejected under 35 U.S.C. §102(b) as being anticipated by the Routh et al. patent 5,735,881. This rejection is also respectfully traversed. Claim 1, as now amended, is clearly allowable over the Routh et al. '881 patent in that it fails to teach or suggest the programmability of a trigger event as presently claimed. Further, the multiple site pacing in programmably selectable sensing channels now provided for in claim 1 constitutes a limitation that is not anticipated by the Routh et al. patent.

In that each of the independent claims 15, 25 and 35 incorporate the concept of target channel programmability whereby sensed events for programmably preselected chamber is provided for, those claims are patentable over the Routh et al. reference.

By way of summary, then, all of the claims remaining in the application are now considered to be in condition for allowance and a Notice to that effect is most earnestly solicited.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing is filed in response to the Official Action of September 27, 2004, in application Serial No. 10/066,989, filed on February 4, 2002, of Tang, et al. entitled "Method and Apparatus for Avoiding Unwanted Sensing In a Cardiac Rhythm Management Device" and a check in the amount of \$678.00 are being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, postage prepaid, on November 18, 2004.

Date of Signature: November 18, 2004

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